UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TAU-SAN CHOU,
ROBERT EISENREICH, JOHN SANFORD,
ALAN BLOWERS, FRANZINE SMITH,
and JOYCE VAN ECK

Appeal No. 2005-0738
Application No. 08/903,944

ON BRIEF[1]

Before GRON, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 73-96, 100, and 112, all of the claims remaining. Claim 73 is representative and reads as follows:

> 73. A transgenic poinsettia plant comprising at least one expression vector, wherein said expression vector comprises at least one foreign gene, and wherein said transgenic poinsettia plant expresses said foreign gene.

[1] A hearing was scheduled for May 3, 2005, but upon reviewing the application, the panel decided that oral argument was unnecessary and vacated the hearing. See 37 CFR 41.47(f).

The examiner relies on the following references:

David et al., "Conservation of T-DNA in Plants Regenerated from Hairy Root Cultures," Bio/Technology, Vol. 2, No. 1, pp. 73-76 (1984)

Ooms et al., "Genetic manipulation in cultivars of oilseed rape (Brassica napus) using Agrobacterium," Theor. Appl. Genet., Vol. 71, No. 2, pp. 325-329 (1985)

Slightom et al., "Isolation and identification of TL-DNA/plant junctions in Convolvulus arvensis transformed by Agrobacterium rhizogenes strain A4," EMBO Journal, Vol. 4, No. 12, pp. 3069-3077 (1985)

Trulson et al., "Transformation of cucumber (Cucumis sativus L.) plants with Agrobacterium rhizogenes," Theor. Appl. Genet., Vol. 73, pp. 11-15 (1986)

Pythoud et al., "Increased virulence of Agrobacterium rhizogenes conferred by the vir region of pTiBo542: Application to genetic engineering of poplar," Bio/Technology, Vol. 5, pp. 1323-1327 (1987)

Sukhapinda et al., "Ri-plasmid as a helper for introducing vector DNA into alfalfa plants," Plant Molecular Biology, Vol. 8, pp. 209-216 (1987)

Rech et al., "Agrobacterium rhizogenes Mediated Transformation of the Wild Soybeans Glycine canescens and G. clandestina: Production of Transgenic Plants of G. canescens," Journal of Experimental Botany, Vol. 39, No. 206, pp. 1275-1285 (1988)

Sinkar et al,, "rolA locus of the Ri plasmid directs developmental abnormalities in transgenic tobacco plants," Genes & Development, Vol. 2, No.6, pp. 688-697 (1988)

Visser et al., "Efficient transformation of potato (Solanum tuberosum L.) using a binary vector in Agrobacterium rhizogenes," Theor. Appl. Genet., Vol. 78, No. 4, pp. 594-600 (1989)

Caesar, "Pathogenicity of Agrobacterium Species from the Noxious Rangeland Weeds Euphorbia esula and Centaurea repens," Plant Disease, Vol. 78, No. 8, pp. 796-800 (1994)

Follansbee et al., "Transformation of Euphorbia lathyris by Agrobacterium rhizogenes," In Vitro, Vol. 31, No. 3, p.72A (1995)

Oran, "Potato Disc Bioassay for some Jordanian Medicinal Plants," Pharmaceutical Biology, Vol. 37, No. 4, pp. 296-299 (1999)

Claims 73-96, 100, and 112 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Claims 73-75, 83, and 85 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of an adequate written description.

We reverse both rejections.

Background

"Since its introduction over 170 years ago, the poinsettia has become the primary potted flowering plant produced and sold in North America." Specification, page 1. Poinsettias are susceptible to insect pests and to infection by bacteria and fungi. Page 2. "Although chemical treatment can control certain of these insect pests and disease pathogens, such treatment can also have an adverse effect upon poinsettias. An alternative to chemical treatment is to genetically engineer transgenic poinsettia that express polypeptides capable of protecting the plant against the insects and pathogens. The production of transgenic plants can further be used to enhance the commercial value of poinsettia by controlling characteristics such as flower color, early flowering, day neutrality, free branching, dwarfness, fragrance, and superior harvest and shipping qualities." Id.

The specification provides several working examples in which poinsettia tissues were transformed with various DNA constructs using the microparticle bombardment method; the transformed tissue was then used to regenerate whole, transgenic poinsettia plants. See pages 42-43 for a general discussion of the method and pages 44-45 for a summary of the DNA constructs used. The specification also provides an

extensive discussion of foreign genes that could enhance the commercial value of transgenic poinsettia plants. See pages 28-42.

Discussion

Claim 73 is directed to a poinsettia plant (i.e., an intact plant as opposed to isolated cells or tissue) that comprises an expression vector that contains a foreign gene that is expressed in the transgenic plant. The examiner rejected the claims for lack of enablement and lack of an adequate written description.

1. Enablement

The examiner rejected all of the pending claims as nonenabled, reasoning that

> the specification, while being enabling for claims limited to transgenic poinsettia plants produced by a method comprising utilizing particle bombardment of embryogenic callus, does not reasonably provide enablement for claims broadly drawn to transgenic poinsettia plants produced by any method including Agrobacterium-mediated transformation.

Examiner's Answer, page 5. The examiner went on to explain why undue experimentation would have been required to use Agrobacterium to transform poinsettias. See id., pages 5-7.

Appellants argue that

> [a]ll that § 112 requires with regard to enablement is the disclosure of a single method by which one of ordinary skill in the art can make and use the claimed plants without undue experimentation. . . . The Examiner has acknowledged that the specification is enabling for claims to transgenic poinsettia plants produced by microprojectile-mediated transformation. . . . Whether the specification also discloses the production of transgenic poinsettia by Agrobacterium-mediated transformation or by any other method is irrelevant to the issue of whether the presently pending transgenic plant claims are enabled.

Appeal Brief, page 3.

Appellants' argument has merit. See Johns Hopkins Univ. v. Cellpro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) ("The enablement requirement is met if the description enables any mode of making and using the invention."). Here, the examiner's concession that the specification is enabling for one method of making the claimed plants – particle bombardment – is fatal to the rejection for nonenablement.

The examiner argues that the cases cited by Appellants[2] do not apply here because plants transformed using Agrobacterium differ from plants transformed through particle bombardment. Specifically, the examiner argues that

> the use of Agrobacterium-based plant transformation vectors results in the integration into the plant nuclear genome of the T-DNA borders, which are 25 base pair long repeated sequences flanking either end of the foreign DNA of interest to be inserted into the plant. . . . The use of an Agrobacterium-based vector comprising the T-DNA borders flanking a foreign disease resistance gene will result in the production of a transformed plant which has the foreign disease resistance gene, flanked by the T-DNA borders, integrated into its nuclear DNA genome. . . . This supports the Examiner's position that the instant claims read on two different products, while the specification only enables a method of making one of the two products.

Examiner's Answer, pages 8-9.

We do not agree with the examiner's reasoning. The issue is not whether the claims read on some embodiments that may be difficult to produce. The issue is whether the specification enables those skilled in the art to do what is claimed; here, to make transgenic poinsettia plants.

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[2] In addition to Johns Hopkins v. Cellpro, Appellants cited Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003), and Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 59 USPQ2d 1238 (Fed. Cir. 2001), for basically the same point.

A claim can be enabled throughout its full scope without enabling every potential embodiment within that scope. See, e.g., CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 68 USPQ2d 1940 (Fed. Cir. 2003). The claims in that case were directed to a "method for the cleaning of semiconductor wafers" but did not specify a standard of cleanliness to be achieved. The claims thus read on commercially viable embodiments; i.e., methods of cleaning semiconductor wafers to a level suitable for commercial use.

The CFMT court, however, held that the patent disclosure did not need to enable a cleaning method that would achieve a commercial standard of cleanliness. See id. at 1338, 68 USPQ2d at 1944. The CFMT court concluded that since the claimed method was not limited to one achieving a specific level of cleanliness, enablement required only that the specification "enable a person of skill in the art to make and use a system or apparatus to achieve any level of contaminant removal without undue experimentation." Id. at 1339, 68 USPQ2d at 1944.

Similarly here, the claims do not specify where the foreign gene resides in the plant cell, nor do they specify whether it is integrated in the genome (with or without flanking sequences). The claims do not require the claimed plants to contain a foreign gene flanked by 25-bp T-DNA sequences, they only require that the plants be transformed with an expressed foreign gene. The examiner has conceded that the specification enables those skilled in the art to make such plants using particle bombardment. The examiner has not explained why more is required for enablement. The rejection for nonenablement is reversed.

2. Description

The examiner rejected claims 73-75, 83, and 85 on the basis that the specification lacks an adequate written description of the claimed subject matter:

> The claims are broadly drawn to any transgenic poinsettia plant which contains any heterologous coding sequence conferring any trait. The heterologous coding sequence, or "foreign gene", is not characterized with respect to source, i.e. bacterial, fungal, viral, animal or plant source, let alone a particular species within each of the above categories. No guidance has been provided for the characterization of a multitude of coding sequences encoding a multitude of proteinaceous or non-proteinaceous products conferring a multitude of traits. Only specific coding sequences conferring disease or insect resistance, herbicide resistance, modified plant habit, ethylene resistance, antibiotic resistance, early flowering, and delayed senescence were provided (see page 2 of the specification . . . , page 3 . . . , page 5 . . . , page 6 . . . , page 12 . . . , page 28 . . . , page 29 . . . , page 30 . . . , page 38 . . . , page 39 . . . , page 40 . . . , page 41 . . . and claims 76, 78 and 95).

Examiner's Answer, page 13. The examiner cited University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), as supporting the rejection.

Appellants argue that Eli Lilly applies only where the claim terms at issue are "new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend." Appeal Brief, page 5 (quoting Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003)). Appellants argue that the claim term "'foreign genes' does not describe new or unknown biological materials that the ordinary skilled artisan would easily misapprehend – one skilled in the art can easily apprehend non-poinsettia genes." Appeal Brief, pages 5-6.

In our view, the examiner has not explained why the specification does not adequately describe the "foreign gene[s]" recited in the claims. The specification provides an extensive list of foreign genes that are suitable for transformation into

poinsettia plants. See pages 28-42. The specification also cites references that show that many of the listed genes were known in the art at the time the present application was filed.

The examiner has acknowledged that the specification provides "specific coding sequences conferring disease or insect resistance, herbicide resistance, modified plant habit, ethylene resistance, antibiotic resistance, early flowering, and delayed senescence," but argues that these sequences are insufficient to describe the genus of "foreign genes" because the genus includes genes that affect other properties, genes that are not described in the specification. See the Examiner's Answer, page 16:

> [T]he specification does not characterize or describe any isolated gene from any organism encoding any protein which would confer [flower color, fragrance, or superior post harvest and shipping qualities]. . . . In addition, the specification does not describe any isolated gene encoding any isolated protein conferring black, yellow, or orange flower color to poinsettias. Moreover, "foreign gene" could encompass those genes encoding proteins which confer increased tissue culturability, frost tolerance, non-green leaf color, or animal defense via thorn production, among countless other non-exemplified genes encoding a multitude of non-exemplified proteins conferring a multitude of non-exemplified functions.

It is well-settled that "[a] specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). Recent decisions by the Court of Appeals for the Federal Circuit have not changed that long-standing rule.

The court in Eli Lilly stated that

> [i]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the

> species that the claims encompass. . . . In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. . . .
>
> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

119 F.3d at 1568, 43 USPQ2d at 1406.

The standard set out in Eli Lilly, however, is not applicable to every set of facts. The court recently considered a written description challenge to claims directed to vertebrate and mammalian host cells containing DNA encoding human erythropoietin. The court concluded that Eli Lilly was "inapposite to th[at] case because the claim terms at issue . . . [were] not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003).

Here, the claims are directed to poinsettia plants transformed with "foreign" (i.e., non-poinsettia) genes. The issue is whether the specification's description of the claimed invention is adequate to show possession of this claimed invention as of the effective filing date (July 31, 1997). The examiner has not alleged that, as of July 1997, persons skilled in the art were unaware of the structure of numerous non-poinsettia genes. The specification need not reproduce what was known to those skilled in the art at the time of filing. See Space Systems/Loral, Inc. v. Lockheed Martin Corp., 2005 WL 901802 (Fed. Cir. April 20, 2005), at *1: "The written description . . . need not include information that is already known and available to the experienced public."

Thus, the facts of this case distinguish it from Eli Lilly. In that case, the claims were directed to cDNAs encoding "vertebrate insulin" or "mammalian insulin" but the specification provided only a single example within either genus (cDNA encoding rat insulin) and no other such sequences were known in the art. See 119 F.3d at 1563, 43 USPQ2d at 1401. Given those facts, the court held that the single species did not adequately describe the genus.

Here, however, the examiner has not contested that those skilled in the art were aware of numerous examples of adequately described, non-poinsettia genes. Thus, the "foreign genes" recited in the claims here are not analogous to the "vertebrate insulin" or "mammalian insulin" cDNAs that were at issue in Eli Lilly. Rather, as in Amgen, the foreign, or non-poinsettia, genes at issue in this case "are not new or unknown biological materials that ordinarily skilled artisans could easily miscomprehend." 314 F.3d at 1332, 65 USPQ2d at 1398.

Summary

The examiner has the initial burden to show unpatentability under the first paragraph of 35 U.S.C. § 112. The examiner has not shown that undue experimentation would have been required to practice the claimed invention, or that the specification fails to show that Appellants were in possession of the claimed invention at the time of filing. The rejections on appeal are therefore reversed.

REVERSED

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